Food and Drug Administration

Adverse Event Expedited Reporting System (AdEERS) Backend System (ABS) FDA Module

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APPLICATION USER'S GUIDE

PRODUCED BY CAPITAL TECHNOLOGY INFORMATION SERVICES, INC.

The *AdEERS Backend System FDA Module User's Guide* was prepared for:
Food and Drug Administration (FDA)

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AdEERS Backend System (ABS) Background

Introduction

Screen overview

The AdEERS Backend System (ABS) is a client-server computer application used to obtain current information on an Adverse Event and support the processing of an Adverse Event including the completion of required assessments. The ABS presents a series of computer screens with open regions in which you select and enter information needed to define and process an Adverse Event. An overview of the ABS associated screens is shown in Figure 1.

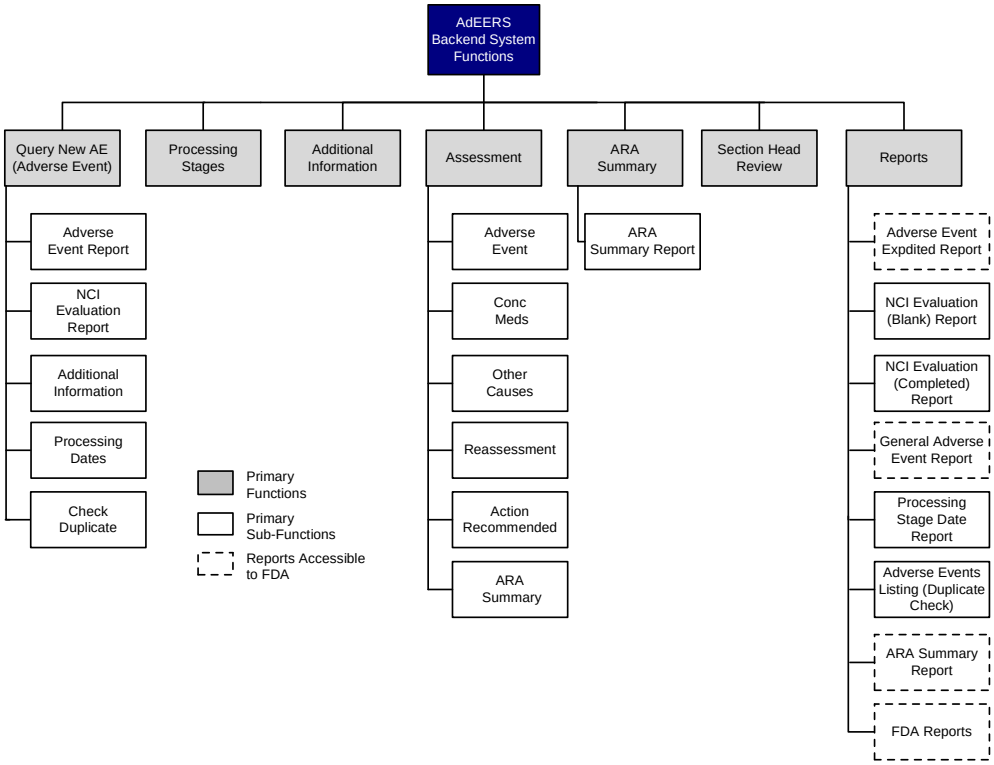


Figure 1: ABS Functional Description

ABS Title Screen	Once you have entered the appropriate user name, password, and database location, the ABS title screen (shown in Figure 2 on page 2) is displayed. The ABS title screen identifies the application and introduces the system menu bar. This system menu bar contains all the menu options that are available in the ABS application.

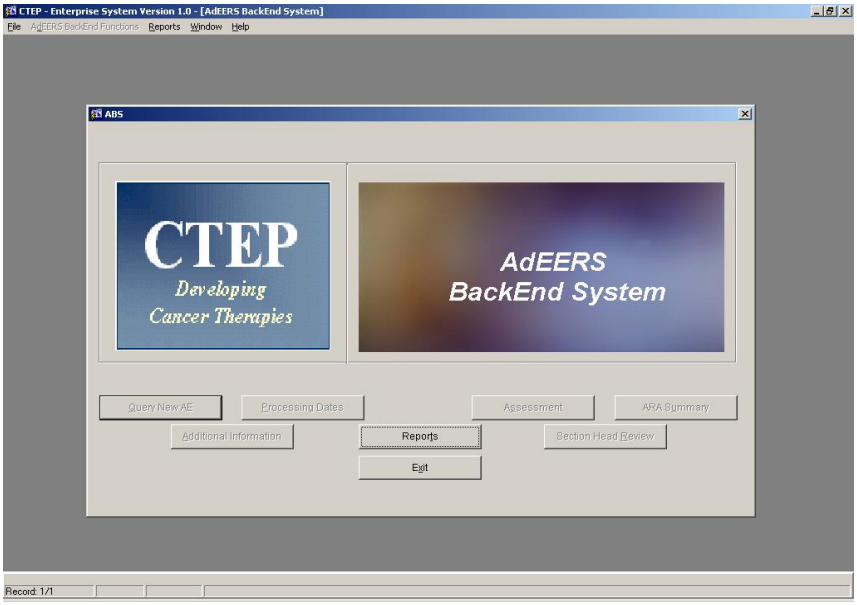


Figure 2: ABS Title Screen

FDA Modules Figure 3 shows the modules accessible to the FDA.

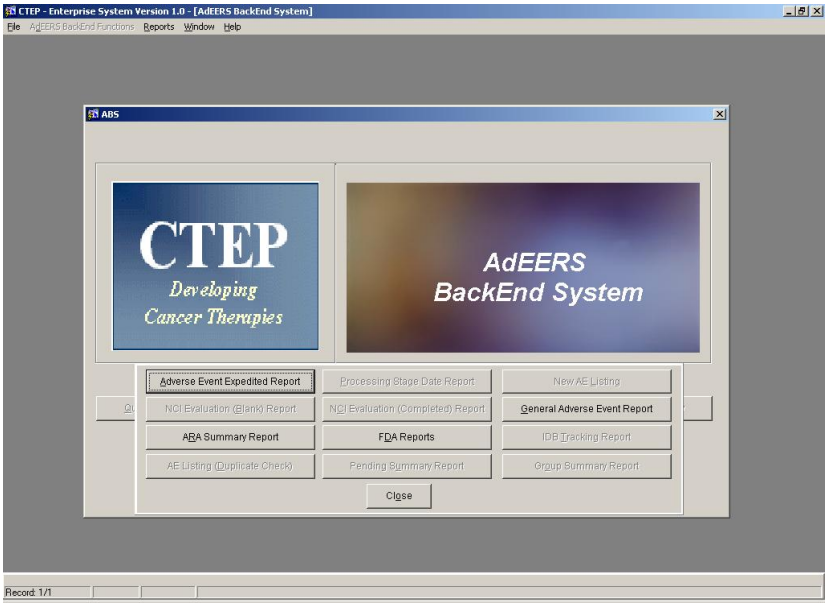


Figure 3: ABS Title Screen Showing Modules Accessible to the FDA

ABS Reports

Overview

Major utilities	The Report function provides access to the utilities to create and print FDA reports. The major utilities are: ▪ Adverse Event Expedited Report ▪ ARA Summary Report ▪ FDA Reports (consisting of Adverse Event Expedited Report and ARA Summary Report) ▪ General Adverse Event Report

Adverse Event Expedited Report

Adverse Event Expedited Report Screen

Parameter Form screen

The Adverse Event Expedited Report Parameter screen (shown in Figure 4) permits you to generate reports for specific Adverse Event Expedited Report information contained within AdEERS.

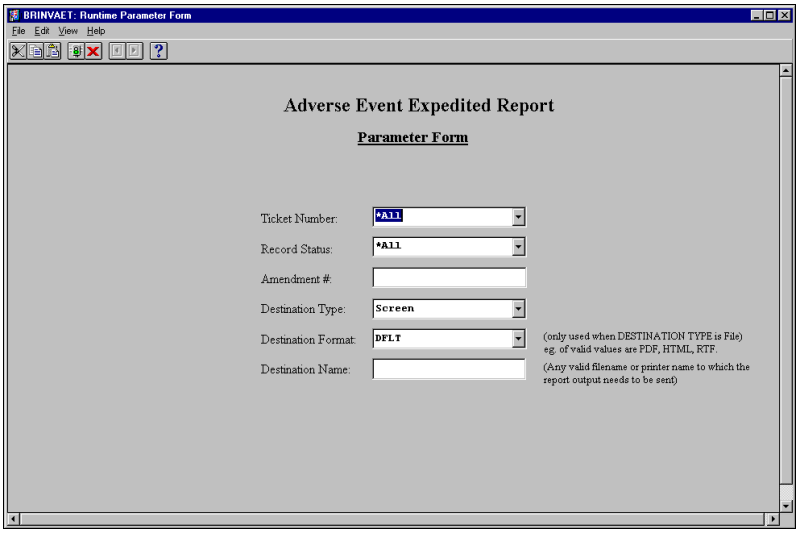


Figure 4: Adverse Event Expedited Report Parameter Form Screen

Note: Selecting the *All option for any of the report fields provides the capability to obtain all records for that field. Care should be taken when using this option as the resulting report may be very large and contain information that you may not want to review.

Entry characteristics

The following text describes the unique entry characteristics of each field in the Adverse Event Expedited Report Parameter screen (Figure 4).

Ticket Number The unique number assigned to the Adverse Event. Click the drop-down arrow to the right of the text to view the **Ticket Number** LOV (shown in Figure 5). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Ticket Number** field populates automatically with the selected value.

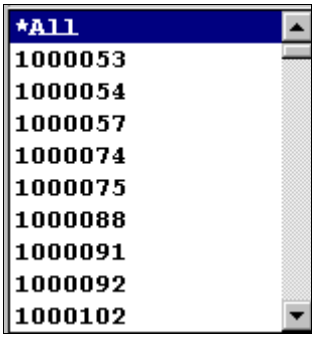


Figure 5: Ticket Number LOV

Record Status The type of report (either original for the initial New Adverse Event) or Amendment if the report reflects a change to the original New Adverse Report. Click the drop-down arrow to the right of the text to view the **Record Status** LOV (shown in Figure 6). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Record Status** field populates automatically with the selected value.

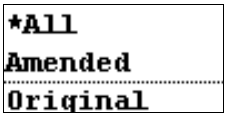


Figure 6: Record Status LOV

Amendment # The desired amendment of the Adverse Event Record. Enter the appropriate numeric characters of the desired amendment.

Destination Type

The destination of the report output (e.g., computer screen, printer, etc.). Click the drop-down arrow to the right of the text to view the **Destination Type** LOV (shown in Figure 7). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Destination Type** field populates automatically with the selected value.

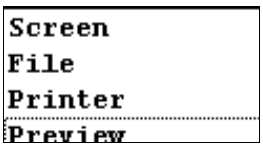


Figure 7: Destination Type LOV

Destination Format

The desired format of the file output. Click the drop-down arrow to the right of the text to view the **Destination Format** LOV (shown in Figure 8). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Destination Format** field populates automatically with the selected value.

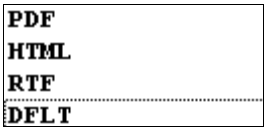


Figure 8: Destination Format LOV

Note: This field is only used when the destination name is a file.

Destination Name

The final destination of the report (e.g., valid filename, printer, etc.). Enter the appropriate path name of the final destination.

Accessing the Adverse Event Expedited Report Screen

Procedure Complete the following steps to access the Adverse Event Expedited Report screen.

Step	Action
1	From the ABS Main screen, click the **Reports** Menu option.
2	Click the **Adverse Event Expedited Report** option on the **Reports** Menu option.
3	The Adverse Event Expedited Report Parameter screen is displayed (see Figure 4).

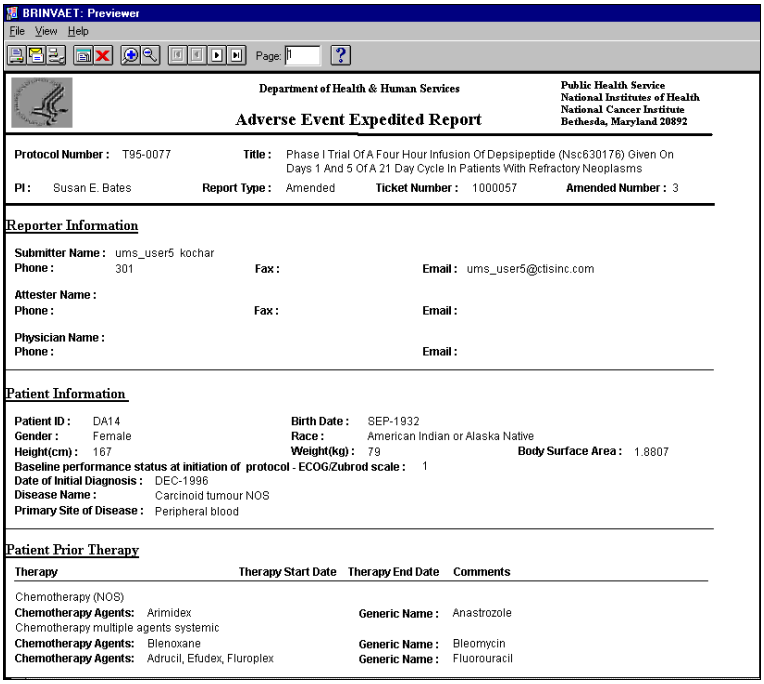
Note: You can also access this report by clicking the **Reports** option in the application main panel. Clicking this option surfaces all report options. Click the **Adverse Event Expedited Report** option to bring up this specific report.

Defining a Report in the Adverse Event Expedited Report Screen

Procedure Complete the following steps to define a report in the Adverse Event Expedited Report screen.

Step	Action
1	Click the drop-down arrow button next to desired report field (i.e., **Ticket Number, Record Status**) to choose from the LOV. Select the appropriate value. The selected value will display in the field. Press **Tab** to move to the next field.
2	Enter the appropriate amendment number in the **Amendment #** field if a specific amendment of the Adverse Event is desired. Press **Tab** to move to the next field.
3	Click the drop-down arrow button next to **Destination Type** field to select a specific report output. Select the desired output by choosing from the LOV. The selected value will display in the field. Press **Tab** to move to the next field. **Note**: Complete the last two fields, **Destination Format** and **Destination Name** only if the **Destination Type** is a file.
4	If the destination type is a file, specify the format of the file in the **Destination Format** field. The following formats are available: • PDF: Portable Document Format • HTML: Hyper Text Message Language • RTF: Rich Text Format Press **Tab** to move to the next field.
5	Enter the name by providing the final designation of the report in the **Destination Name** field. This action is accomplished by providing the full path to the file or printer or the designated party's complete electronic mail address.
6	Execute the report by selecting the **Run Report** value under the **File** option of the print menu bar or my selecting the stoplight icon on the menu bar. Generate the report by selecting the **Run Report** toolbar option. A sample of a final report is provided in Figure 9.

Report sample


BRINVAET: Previewer

File View Help

Page: 1

Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Adverse Event Expedited Report

Protocol Number : T95-0077 **Title :** Phase I Trial Of A Four Hour Infusion Of Depsipeptide (Nsc630176) Given On Days 1 And 5 Of A 21 Day Cycle In Patients With Refractory Neoplasms

PI : Susan E. Bates **Report Type :** Amended **Ticket Number :** 1000057 **Amended Number :** 3

Reporter Information

Submitter Name : ums_user5 kochar
Phone : 301 **Fax :** **Email :** ums_user5@ctisinc.com

Attester Name :
Phone : **Fax :** **Email :**

Physician Name :
Phone : **Email :**

Patient Information

Patient ID : DA14 **Birth Date :** SEP-1932
Gender : Female **Race :** American Indian or Alaska Native
Height(cm) : 167 **Weight(kg) :** 79 **Body Surface Area :** 1.8807
Baseline performance status at initiation of protocol - ECOG/Zubrod scale : 1
Date of Initial Diagnosis : DEC-1996
Disease Name : Carcinoid tumour NOS
Primary Site of Disease : Peripheral blood

Patient Prior Therapy

Therapy	Therapy Start Date	Therapy End Date	Comments
Chemotherapy (NOS)			
Chemotherapy Agents: Arimidex		**Generic Name :** Anastrozole	
Chemotherapy multiple agents systemic			
Chemotherapy Agents: Blenoxane		**Generic Name :** Bleomycin	
Chemotherapy Agents: Adrucil, Efudex, Fluroplex		**Generic Name :** Fluorouracil	

Figure 9: Adverse Event Expedited Report Sample

ARA Summary Report

ARA Summary Report Screen

Parameter Form screen

The Adverse Reaction Assessment (ARA) Summary Report Parameter screen (shown in Figure 10) permits you to generate reports for ARA Summary information contained within AdEERS.

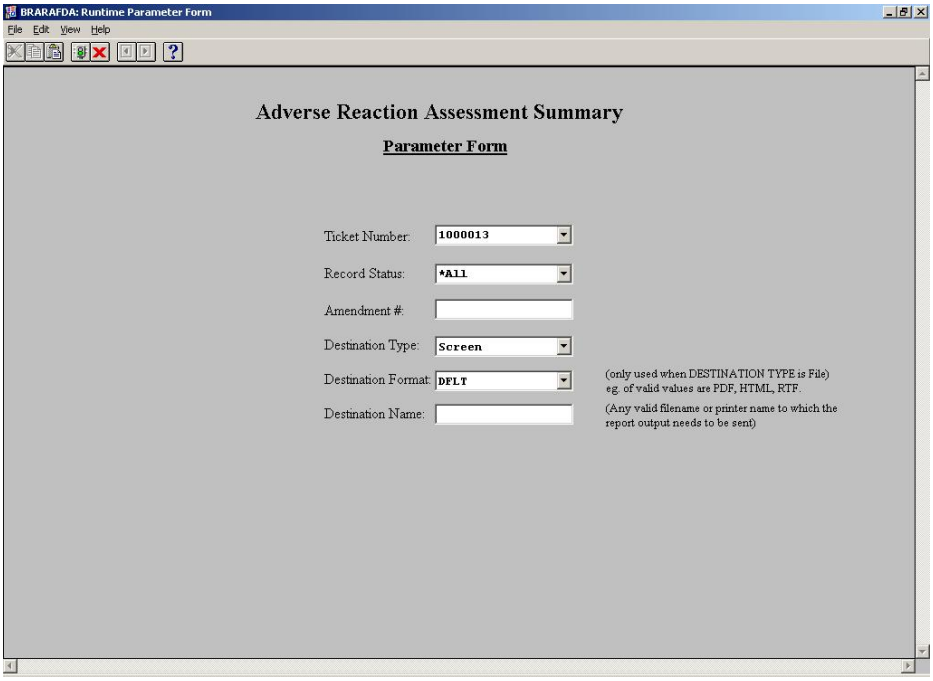


Figure 10: Parameter Screen for ARA Summary Report

Note: Selecting the *All option for any of the report fields provides the capability to obtain all records for that field. Care should be taken when using this option as the resulting report may be very large and contain information that you may not want to review.

Entry characteristics

The following text describes the unique entry characteristics of each field in the ARA Summary Report Parameter screen (Figure 10).

Ticket Number The unique number assigned to the Adverse Event. Click the drop-down arrow to the right of the text to view the **Ticket Number** LOV (shown in Figure 11). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Ticket Number** field populates automatically with the selected value.

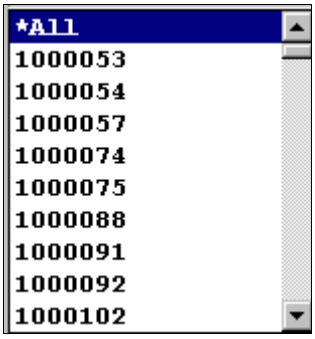


Figure 11: Ticket Number LOV

Record Status The type of report (either original for the initial New Adverse Event) or Amendment if the report reflects a change to the original New Adverse Report. Click the drop-down arrow to the right of the text to view the **Record Status** LOV (shown in Figure 12). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Record Status** field populates automatically with the selected value.

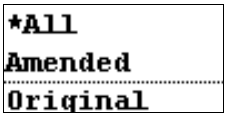


Figure 12: Record Status LOV

Amendment # The desired amendment of the Adverse Event Record. Enter the appropriate numeric characters of the desired amendment.

Destination Type

The destination of the report output (e.g., computer screen, printer, etc.). Click the drop-down arrow to the right of the text to view the **Destination Type** LOV (shown in Figure 13). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Destination Type** field populates automatically with the selected value.

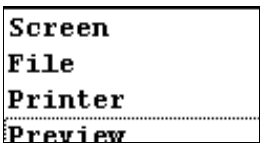


Figure 13: Destination Type LOV

Destination Format

The desired format of the file output. Click the drop-down arrow to the right of the text to view the **Destination Format** LOV (shown in Figure 14). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Destination Format** field populates automatically with the selected value.

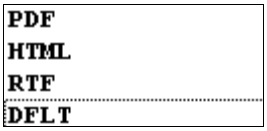


Figure 14: Destination Format LOV

Note: This field is only used when the destination name is a file.

Output Name

The final destination of the report (e.g., valid filename, printer, etc.). Enter the appropriate path name of the final destination.

Accessing the ARA Summary Report Screen

Procedure Complete the following steps to access the ARA Summary Report Parameter screen.

Step	Action
1	From the ABS Main screen, click the **Reports** Menu option.
2	Click the **ARA Summary Report** option on the **Reports** Menu option.
3	The Adverse Reaction Assessment Summary Report Parameter screen is displayed (shown in Figure 10).

Note: You can also access this report by clicking the **Reports** option in the application main panel. Clicking this option surfaces all report options. Click the **ARA Summary Report** option to bring up this specific report.

Defining a Report in the ARA Summary Report Screen

Procedure Complete the following steps to define a report in the ARA Summary Report screen.

Step	Action
1	Click the drop-down arrow button next to desired report field (i.e., **Ticket Number, Record Status**) to choose from the LOV. Select the appropriate value. The selected value will display in the field. Press **Tab** to move to the next field.
2	Enter the appropriate amendment number in the **Amendment #** field if a specific amendment of the Adverse Event is desired. Press **Tab** to move to the next field.
3	Click the drop-down arrow button next to **Destination Type** field to select a specific report output. Select the desired output by choosing from the LOV. The selected value will display in the field. Press **Tab** to move to the next field. **Note**: Complete the last two fields, **Destination Format** and **Destination Name** only if the **Destination Type** is a file.
4	If the destination type is a file, specify the format of the file in the **Destination Format** field. The following formats are available: ▪ PDF: Portable Document Format ▪ HTML: Hyper Text Message Language ▪ RTF: Rich Text Format Press **Tab** to move to the next field.
5	Enter the name by providing the final designation of the report in the **Destination Name** field. This action is accomplished by providing the full path to the file or printer or the designated party's complete electronic mail address.
6	Execute the report by selecting the **Run Report** value under the **File** option of the print menu bar or my selecting the stoplight icon on the menu bar. Generate the report by selecting the **Run Report** toolbar option. A sample of a final report is provided in Figure 15.

Report sample

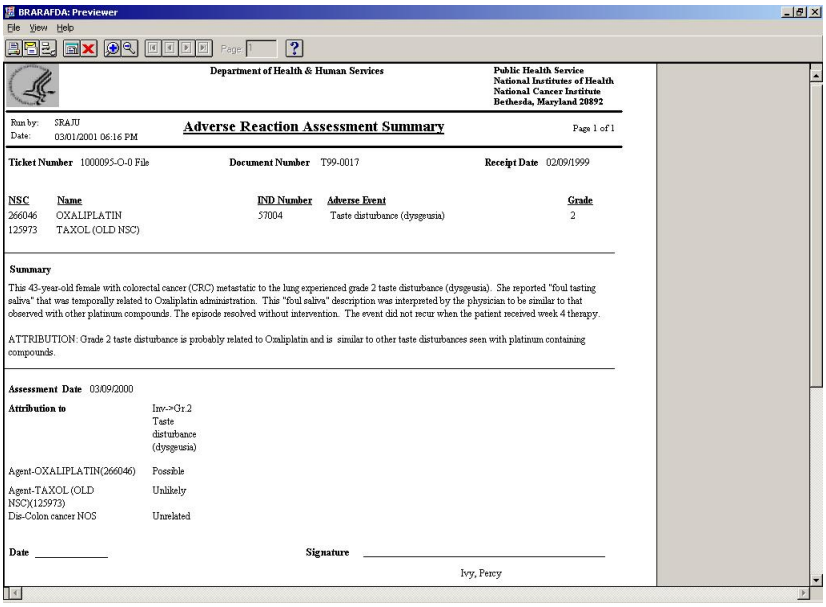


Figure 15: ARA Summary Report Sample

FDA Reports Screen

Parameter Form screen

The FDA Reports Parameter Form screen (shown in Figure 16) permits you to generate the Adverse Event Expedited and Adverse Reaction Assessment Summary reports within AdEERS.

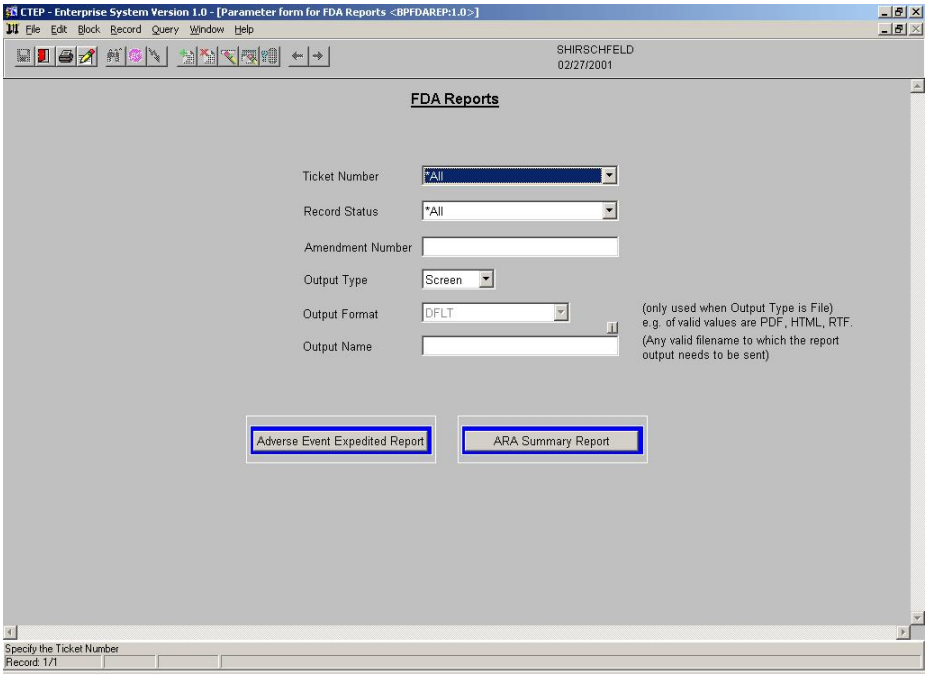


Figure 16: Parameter Screen for accessing either Adverse Event Expedited Report or ARA Summary Report

Note: Selecting the *All option for any of the report fields provides the capability to obtain all records for that field. Care should be taken when using this option as the resulting report may be very large and contain information that you may not want to review.

Entry characteristics

The following text describes the unique entry characteristics of each field in the FDA Reports Parameter screen (Figure 16).

Ticket Number

The unique number assigned to the Adverse Event. Click the drop-down arrow to the right of the text to view the **Ticket Number** LOV (shown in Figure 17). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Ticket Number** field populates automatically with the selected value.

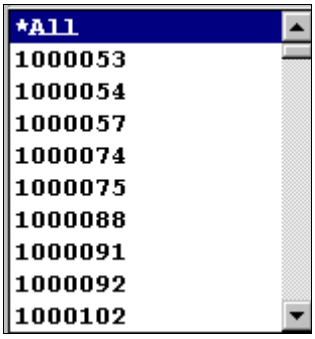


Figure 17: Ticket Number LOV

Record Status

The type of report (either original for the initial New Adverse Event) or Amendment if the report reflects a change to the original New Adverse Report. Click the drop-down arrow to the right of the text to view the **Record Status** LOV (shown in Figure 18). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Record Status** field populates automatically with the selected value.

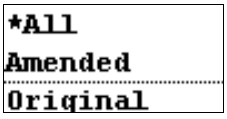


Figure 18: Record Status LOV

Amendment Number

The desired amendment of the Adverse Event Record. Enter the appropriate numeric characters of the desired amendment.

Output Type

The destination of the report output (e.g., computer screen, printer, etc.). Click the drop-down arrow to the right of the text to view the **Output Type** LOV (shown in Figure 19). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Output Type** field populates automatically with the selected value.

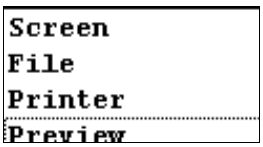


Figure 19: Output Type LOV

Output Format

The desired format of the file output. Click the drop-down arrow to the right of the text to view the **Output Format** LOV (shown in Figure 20). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Output Format** field populates automatically with the selected value.

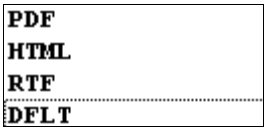


Figure 20: Output Format LOV

Note: This field is only used when the output name is a file.

Output Name

The final output name of the report (e.g., valid filename, printer, etc.). Enter the appropriate path name of the final destination.

Accessing the FDA Reports Screen

Procedure Complete the following steps to access the FDA Reports screen.

Step	Action
1	From the ABS Main screen, click the **Reports** Menu option.
2	Click the **FDA Reports** option on the **Reports** Menu option.
3	The FDA Reports Parameter screen is displayed (see Figure 16 on page 16).

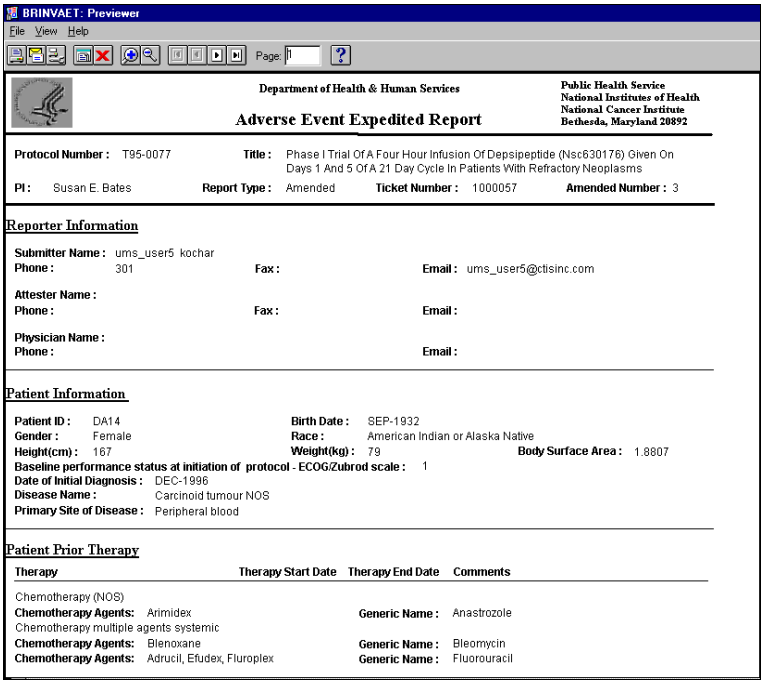
Note: You can also access this report by clicking the **Reports** option in the application main panel. Clicking this option surfaces all report options. Click the **FDA Reports** option to bring up this specific report.

Defining a Report in the FDA Reports Screen

Procedure Complete the following steps to define a report in the FDA Reports screen.

Step	Action
1	Click the drop-down arrow button next to desired report field (i.e., **Ticket Number, Record Status**) to choose from the LOV. Select the appropriate value. The selected value will display in the field. Press **Tab** to move to the next field.
2	Enter the appropriate amendment number in the **Amendment Number** field if a specific amendment of the Adverse Event is desired. Press **Tab** to move to the next field.
3	Click the drop-down arrow button next to **Output Type** field to select a specific report output. Select the desired output by choosing from the LOV. The selected value will display in the field. Press **Tab** to move to the next field. **Note**: Complete the last two fields, **Output Format** and **Output Name** only if the **Output Type** is a file.
4	If the destination type is a file, specify the format of the file in the **Output Format** field. The following formats are available: • PDF: Portable Document Format • HTML: Hyper Text Message Language • RTF: Rich Text Format Press **Tab** to move to the next field.
5	Enter the name by providing the final designation of the report in the **Output Name** field. This action is accomplished by providing the full path to the file or printer or the designated party's complete electronic mail address.
6	Choose a report by clicking the **Adverse Event Expedited Report** or **ARA Summary Report** button. A sample of the final reports is provided in Figure 21 and Figure 22.

Report samples



BRINVAET: Previewer

File View Help

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Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Adverse Event Expedited Report

Protocol Number : T95-0077 **Title :** Phase I Trial Of A Four Hour Infusion Of Depsipeptide (Nsc630176) Given On Days 1 And 5 Of A 21 Day Cycle In Patients With Refractory Neoplasms

PI : Susan E. Bates **Report Type :** Amended **Ticket Number :** 1000057 **Amended Number :** 3

Reporter Information

Submitter Name : ums_user5 kochar
Phone : 301 **Fax :** **Email :** ums_user5@ctisinc.com

Attester Name :
Phone : **Fax :** **Email :**

Physician Name :
Phone : **Email :**

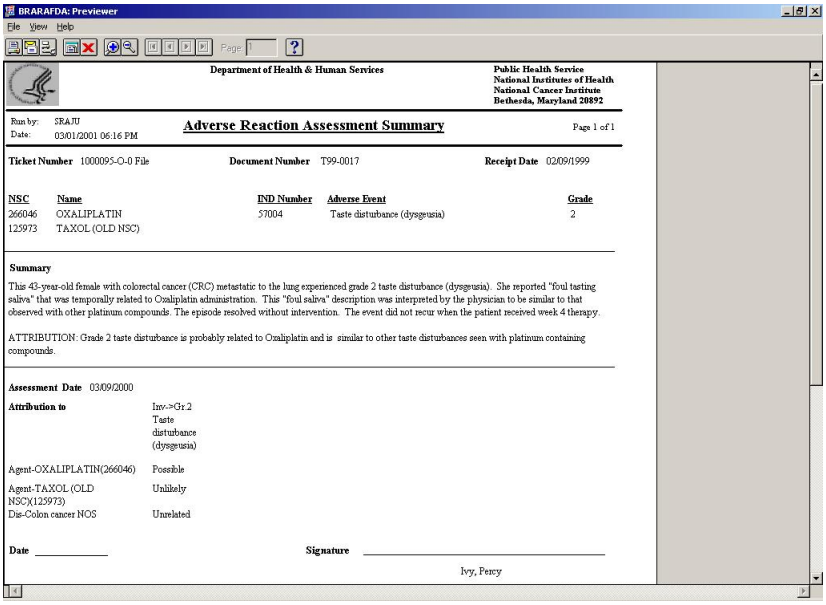
Patient Information

Patient ID : DA14 **Birth Date :** SEP-1932
Gender : Female **Race :** American Indian or Alaska Native
Height(cm) : 167 **Weight(kg) :** 79 **Body Surface Area :** 1.8807
Baseline performance status at initiation of protocol - ECOG/Zubrod scale : 1
Date of Initial Diagnosis : DEC-1996
Disease Name : Carcinoid tumour NOS
Primary Site of Disease : Peripheral blood

Patient Prior Therapy

Therapy	Therapy Start Date	Therapy End Date	Comments
Chemotherapy (NOS)			
Chemotherapy Agents: Arimidex		**Generic Name :** Anastrozole	
Chemotherapy multiple agents systemic			
Chemotherapy Agents: Blenoxane		**Generic Name :** Bleomycin	
Chemotherapy Agents: Adrucil, Efudex, Fluroplex		**Generic Name :** Fluorouracil	

Figure 21: Adverse Event Expedited Report Sample



BRARAFDA: Previewer

File View Help

Page:

Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Run by: SRAJU
Date: 03/01/2001 06:16 PM

Adverse Reaction Assessment Summary

Page 1 of 1

Ticket Number 1000095-O-0 File **Document Number** T99-0017 **Receipt Date** 02/09/1999

NSC	Name	IND Number	Adverse Event	Grade
266046	OXALIPLATIN	57004	Taste disturbance (dysgeusia)	2
125973	TAXOL (OLD NSC)			

Summary

This 43-year-old female with colorectal cancer (CRC) metastatic to the lung experienced grade 2 taste disturbance (dysgeusia). She reported "foul tasting saliva" that was temporally related to Oxaliplatin administration. This "foul saliva" description was interpreted by the physician to be similar to that observed with other platinum compounds. The episode resolved without intervention. The event did not recur when the patient received week 4 therapy.

ATTRIBUTION: Grade 2 taste disturbance is probably related to Oxaliplatin and is similar to other taste disturbances seen with platinum containing compounds.

Assessment Date 03/09/2000

Attribution to	Inv->Gr.2 Taste disturbance (dysgeusia)
Agent-OXALIPLATIN(266046)	Possible
Agent-TAXOL (OLD NSC)(125973)	Unlikely
Dis-Colon cancer NOS	Unrelated

Date _____ **Signature** _____

Ivy, Percy

Figure 22: ARA Summary Report Sample

General Adverse Event Report

General Adverse Event Report Screen

Query criteria

The Query Criteria for General Adverse Event Report screen (shown in Figure 23) within the **Reports** menu option permits you to define and generate reports related to the historical information when the Adverse Event has completed various processing stages.

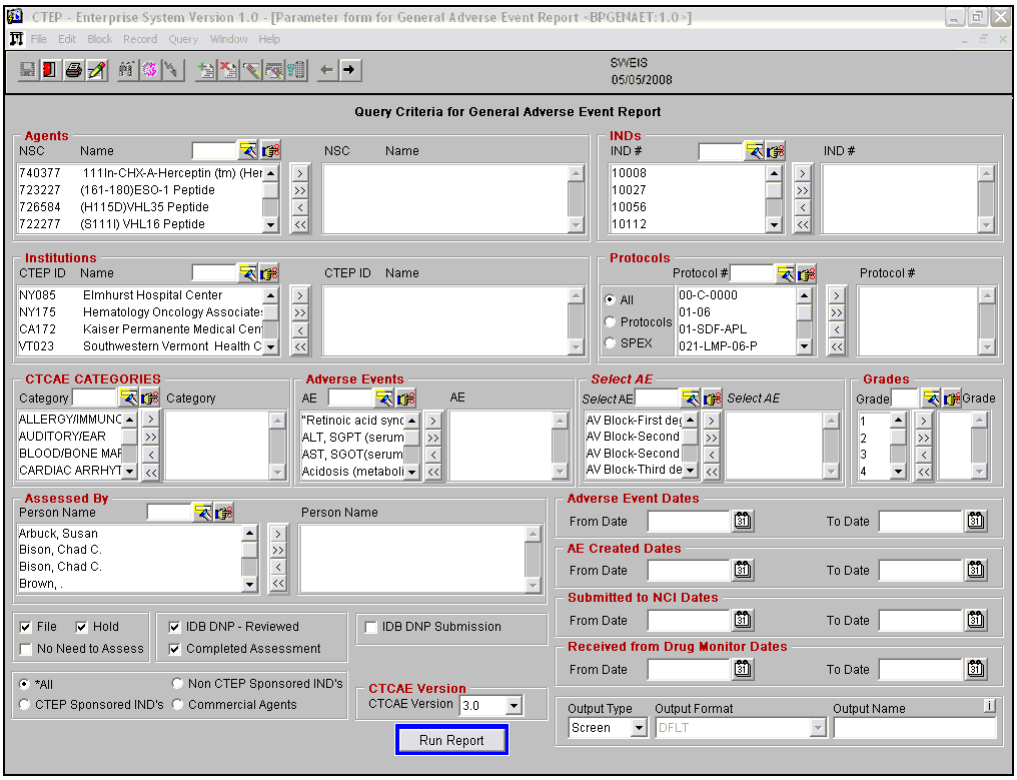


Figure 23: Query Criteria for General Adverse Report screen

Entry characteristics

The following text describes the unique entry characteristics of each field in the Query Criteria for General Adverse Report screen (Figure 23).

NSC Name

The unique number and name of an agent. Select from the **NSC Name** LOV (shown in Figure 24) by positioning the mouse over the desired value and clicking once. Use the single and double left and right arrows to the right of the LOV and flashlight and hand icons above the LOV to complete your search and make your selection.

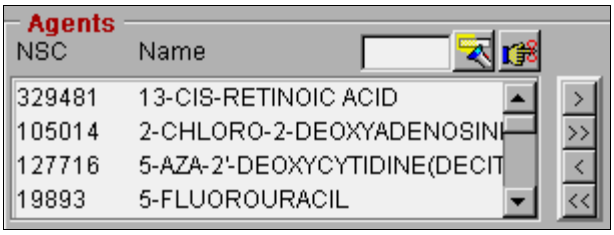


Figure 24: NSC Name LOV

IND #

The unique Investigational New Drug (IND) number assigned by CTEP. Select from the **IND #** LOV (shown in Figure 25) by positioning the mouse over the desired value and clicking once. Use the single and double left and right arrows to the right of the LOV and flashlight and hand icons above the LOV to complete your search and make your selection.

Figure 25: INDs LOV

CTEP ID

The unique CTEP identifier for the organization. Select from the **CTEP ID** LOV (shown in Figure 26) by positioning the mouse over the desired value and clicking once. Use the single and double left and right arrows to the right of the LOV and the flashlight and hand icons above the LOV to complete your search and make your selection.

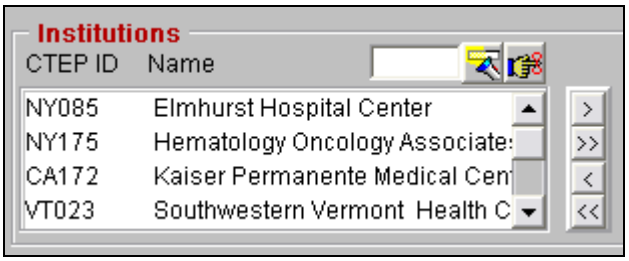


Figure 26: CTEP ID LOV

Protocol #

The CTEP-recognized protocol number. Select from the **Protocol #** LOV (shown in Figure 27) by positioning the mouse over the desired value and clicking once. Use the single and double left and right arrows to the right of the LOV and the flashlight and hand icons above the LOV to complete your search and make your selection.

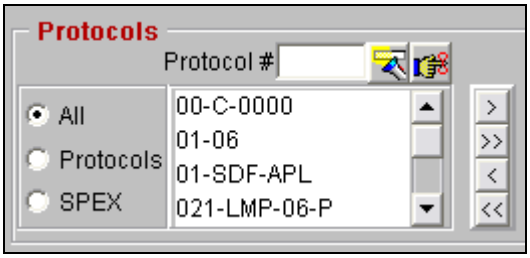


Figure 27: Protocol #

Category

The CTCAE-recognized category for the Adverse Event. Select from the **Category** LOV (shown in Figure 28) by positioning the mouse over the desired value and clicking once. Use the single and double left and right arrows to the right of the LOV and the flashlight and hand icons above the LOV to complete your search and make your selection.

Figure 28: Category LOV

Adverse Events

The recognized name of the Adverse Event. Select from the **Adverse Event** LOV (shown in Figure 29) by positioning the mouse over the desired value and clicking once. Use the single and double left and right arrows to the right of the LOV and the flashlight and hand icons above the LOV to complete your search.

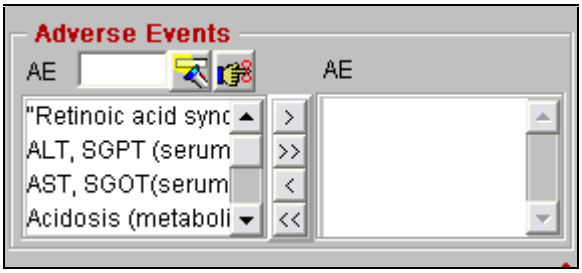


Figure 29: Adverse Event LOV

Select AE

If a further classification of an Adverse Event needs to be documented, that data is entered in the **Select AE** field.
Select from the **Select AE** LOV (shown in **Error! Reference source not found.**) by positioning the mouse over the desired value and clicking once. Use the single and double left and right arrows to the right of the LOV and flashlight and hand icons above the LOV to complete your search.

Figure 30: **Select AE LOV**

Grades

The severity level of the Adverse Event, with 1 being the lowest level of severity and 5 being the highest level of severity.

Select from the **Grade** LOV (shown in **Error! Reference source not found.**) by positioning the mouse over the desired value and clicking once. Use the single and double left and right arrows to the right of the LOV and flashlight and hand icons above the LOV to complete your search.

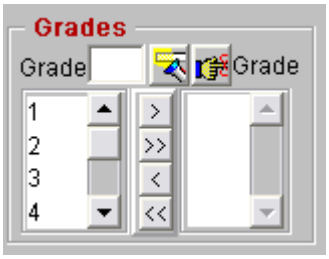


Figure 31: **Grades LOV**

Assessed By

The name of the individual who completed the Adverse Event assessment. Select from the **Person Name** LOV (shown in **Error! Reference source not found.**) by positioning the mouse over the desired value and clicking once. Use the single and double left and right arrows to the right of the LOV and flashlight and hand icons above the LOV to complete your search.

Figure 32: Person Name LOV

Adverse Event Dates

The date when the Adverse Event was completed. These dates represents the earliest date ranges that you want the application to check when performing the search. Enter the date in the **MM/DD/YYYY** format or use the calendar (shown in **Error! Reference source not found.**) provided with the calendar list button to select the appropriate date.

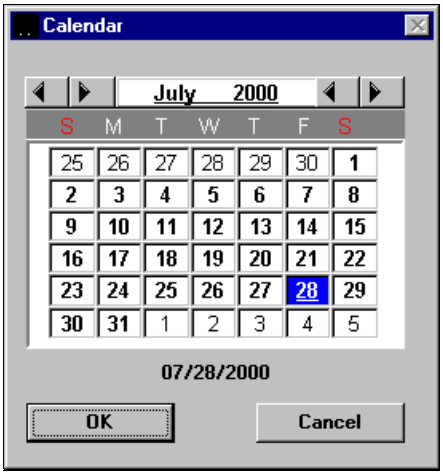


Figure 33: Calendar

AE Created Dates

The date when the Adverse Event was completed. These dates represents the earliest date ranges that you want the application to check when performing the search. Enter the date in the **MM/DD/YYYY** format or uses the calendar (shown in **Error! Reference source not found.**) provided with the drop-down list button to select the appropriate date.

Figure 34: Calendar

Submitted to NCI Dates

The date that the ticket was submitted to NCI. These dates represent the earliest date ranges that you want the application to check when performing the search. Enter the date in the **MM/DD/YYYY** format or uses the calendar (shown in Figure 36:) provided with the drop-down list button to select the appropriate date.

Figure 35: Calendar

Received From Drug Monitor Dates

The date when the Adverse Event was received from the Drug Monitor. These dates represents the earliest date ranges that you want for the application to check when performing the search. Enter the date in the MM/DD/YYYY format or uses the calendar (shown in Figure 36:) provided with the drop-down list button to select the appropriate date.

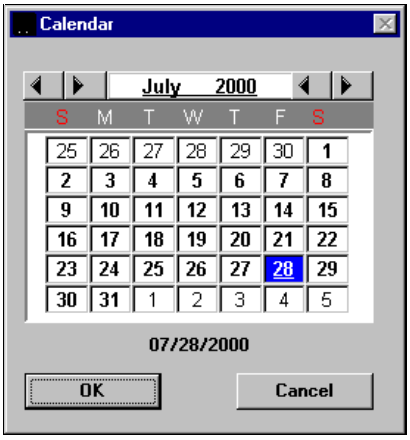


Figure 36: Calendar

Output Type

The type of output (to the screen, to a file, etc.). Click the drop-down arrow to the right of the text to view the **Output Type** LOV (shown in Figure 37). Select from the LOV by positioning the mouse over the desired value and clicking once. The **Output Type** field populates automatically with the selected value.

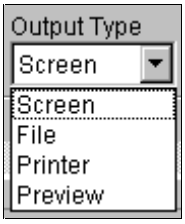


Figure 37: Output Type

Output Format The desired format of the file (if the desired destination type is a file). Click the drop-down arrow to the right of the text to view the **Output Format** LOV (shown in Figure 38). Select from the LOV by positioning the mouse over the desired value and clicking once. The Output Format field populates automatically with the selected value.

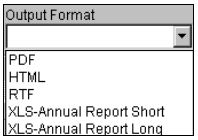


Figure 38: Output Format

Output Name The name of the file (if the desired destination type is a file). Enter file name include entire path including extensions.

Accessing the General Adverse Event Report Screen

Procedure Complete the following steps to access the General Adverse Event Report screen:

Step	Action
1	From the ABS Main screen, click the Reports button. The Reports dialog box is displayed.
2	Click the General Adverse Event Report button. The Query Criteria for General Adverse Event Report is displayed (see Figure 23 on page 22).

Defining a Report in the General Adverse Event Report Screen

Procedure Complete the following steps to define a Report in the General Adverse Event Report screen.

Step	Action
1	Enter the appropriate report parameters by selecting the desired value within the respective fields. The left side list is the available parameter options and the right side list is the selected parameters for the report. Several mechanisms have been provided to help you select the desired parameters. The first group of icons are the flashlight and hand icons: ▪ Flashlight icon finds the item entered in the field from the list. ▪ Hand icon finds the next match of the item entered in the field from the list. The second mechanism is the arrow icons. This mechanism permits the selection of the desired criteria, which is displayed in the right frame of each criteria field (see **Error! Reference source not found.**9).

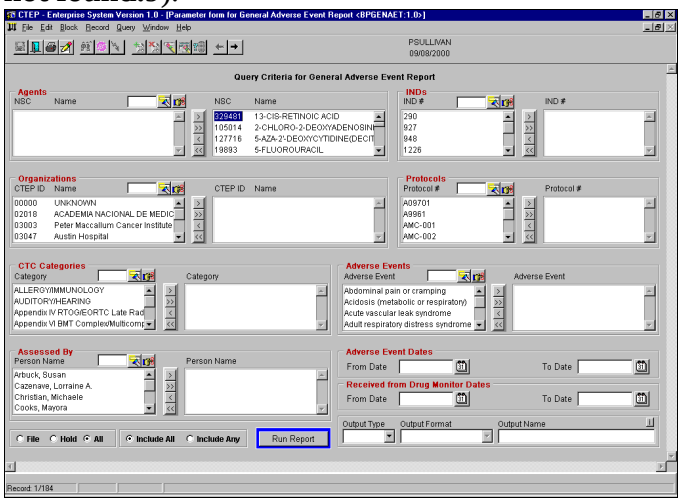


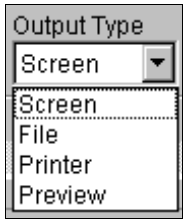
Figure 39: Selected criteria in right frame

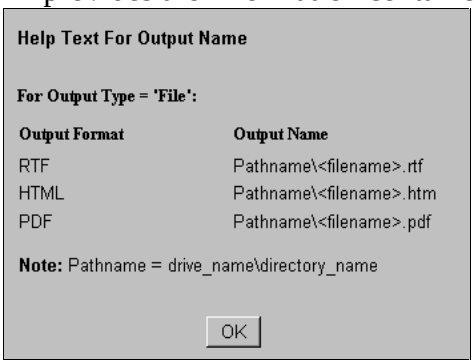
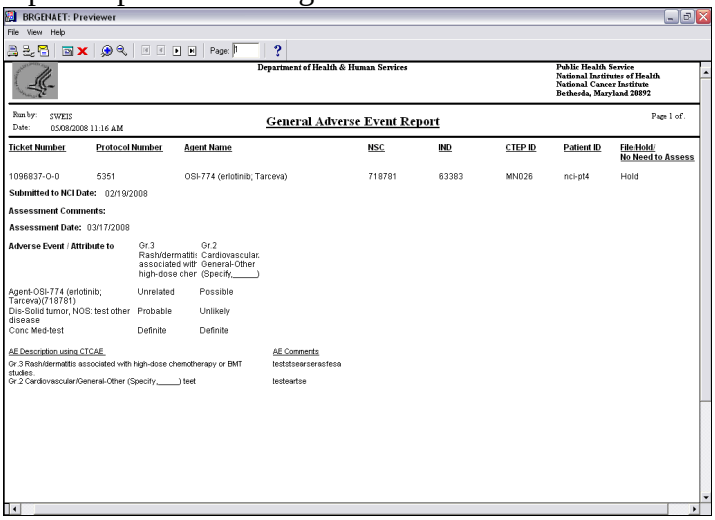
The actions related to each arrow icon are provided below:

The single > arrow selects one highlighted record from left to right.

The double >> arrows select all records from left to right.

The single < arrow deselects one record from right to left.

Step	Action
	 The double << arrows deselect all records from right to left.
2	Press **Tab** to move to the next field. For the **Adverse Event Dates**, **AE Created Dates**, **Submitted to NCI Dates**, and **Received from the Drug Monitor Dates** fields, select the respective **From Date** and **To Date** from the respective calendar drop-down buttons.
3	Select the desired option buttons and checkboxes (shown in Figure 40) to focus the query. Press **Tab** to move to the next field.  **Figure 40: Query Output buttons** **Note**: For **Include Any** option: This option is only for Agents, INDs, Organizations, Protocols, CTC Categories, Adverse Events and Assessed By.
4	Click the drop-down arrow button next to **Output Type** field to select a specific report output. Select the desired output by choosing from the LOV. The selected value will display in the field.  **Figure 41: Output Type**
5	If the output type is a file, specify the format of the file in the **Output Format** field. The following formats are available: ▪ PDF: Portable Document Format ▪ HTML: Hyper Text Message Language ▪ RTF: Rich Text Format ▪ XLS – Annual Report Short: Prints output in Excel spreadsheet column format (short form) ▪ XLS – Annual Report Long: Prints output in Excel spreadsheet column format (long form) ▪ DFLT: The Default selection ▪ XLS AE Summary Report: Prints output of the Adverse Event Report in Excel spreadsheet column format

Step	Action
6	Press **Tab** to move to the next field. Enter the name in the **Output Name** field. Be sure to provide the full path to the file or printer or the designated party's complete email address. Information related to the required path name is provided in the Help button located just above the **Output Name** field. Figure 42 provides the information contained in this help file.  **Help Text For Output Name** **For Output Type = 'File':** **Output Format** — **Output Name** RTF — Pathname\<filename>.rtf HTML — Pathname\<filename>.htm PDF — Pathname\<filename>.pdf **Note:** Pathname = drive_name\directory_name OK **Figure 42: Output Name Help File**
7	Generate the report by selecting the **Run Report** button Run Report or selecting the **Run Report** toolbar option. A sample report is provided in Figure 43.  BRGENAET: Previewer File View Help Department of Health & Human Services Public Health Service National Institutes of Health National Cancer Institute Bethesda, Maryland 20892 Run by: SWEIS Date: 05/08/2008 11:16 AM General Adverse Event Report Page 1 of Ticket Number: 1096837-O-0 — Protocol Number: 5351 — Agent Name: OSI-774 (erlotinib; Tarceva) — NSC: 718781 — IND: 63383 — CTEP ID: MN026 — Patient ID: nci-pt4 — File/Hold/No Need to Assess: Hold Submitted to NCI Date: 02/19/2008 Assessment Comments: Assessment Date: 03/17/2008 Adverse Event / Attribute to — Gr.3 Rash/dermatitis associated with high-dose cher — Gr.2 Cardiovascular, General-Other (Specify,_____) Agent-OSI-774 (erlotinib; Tarceva)(718781) — Unrelated — Possible Dis-Solid tumor, NOS: test other disease — Probable — Unlikely Conc Med-test — Definite — Definite AE Description using CTCAE — AE Comments Gr.3 Rash/dermatitis associated with high-dose chemotherapy or BMT studies — teststseaerseasfesa Gr.2 Cardiovascular/General-Other (Specify,_____) teet — testeartse **Figure 43: General Adverse Event Report sample**